

COMPARISON OF 2006 REGULATIONS AND 2007 REGULATORY CHANGES

to

PART 482 – CONDITIONS OF PARTICIPATION FOR HOSPITALS

482.13 Condition of Participation: Patient's Rights Standards (e) and (f) and the new Standard (g)

EFFECTIVE January 8, 2007

The January 8, 2007 revisions begin with Standard (e). In order to focus on the changes in wording of the new regulations the 2006 tags may be entered out of order. Standards (e) & (f) have been combined and Standard (f) has been completely re-written to address staff training requirements.

TAG	2006 Regulation	Regulation Effective January 8, 2007
A-0062	§482.13 (e) Standard: Restraint for Acute Medical and Surgical Care	(e) Standard: <i>Restraint or seclusion.</i>
A-0063	<p>(e)(1) The patient has the right to be free from restraints of any form that are not medically necessary or are used as a means of coercion, discipline, convenience, or retaliation by staff.</p> <p>The term "restraint" includes either a physical restraint or a drug that is being used as a restraint.</p> <p>A physical restraint is any manual method or physical or mechanical device, material, or equipment attached or adjacent to the patient's body that he or she cannot easily remove that restricts freedom of movement or normal access to one's body.</p> <p>A drug used as a restraint is a medication used to control behavior or to restrict the patient's freedom of movement, and is not a standard treatment for the patient's medical or psychiatric condition.</p>	<p>All patients have the right to be free from physical or mental abuse, and corporal punishment. All patients have the right to be free from restraint or seclusion, of any form, imposed as a means of coercion, discipline, convenience, or retaliation by staff.</p> <p>Restraint or seclusion may only be imposed to ensure the immediate physical safety of the patient, a staff member, or others and must be discontinued at the earliest possible time.</p> <p>(Ref. deleted tag A-0077)</p>
		<p>(e)(1) Definitions.</p> <p>(i) A restraint is—</p> <p>↓ (A) Any manual method, physical or mechanical device, material, or equipment that immobilizes or reduces the ability of a patient to move his or her arms, legs, body, or head freely; or</p>
		<p>↓ (B) A drug or medication when it is used as a restriction to manage the patient's behavior or restrict the patient's freedom of movement and is not a standard treatment or dosage for the patient's condition.</p>

TAG	2006 Regulation	Regulation Effective January 8, 2007
		<p>(C) A restraint <u>does not</u> include devices, such as</p> <ul style="list-style-type: none"> • orthopedically prescribed devices, • surgical dressings or bandages, • protective helmets, • or other methods that involve the physical holding of a patient for the purpose of conducting routine physical examinations or tests, • or to protect the patient from falling out of bed, • or to permit the patient to participate in activities without the risk of physical harm (this does not include a physical escort).
		<p>(ii) <u>Seclusion</u> is the involuntary confinement of a patient alone in a room or area from which the patient is physically prevented from leaving.</p> <p>Seclusion may only be used for the management of violent or self destructive behavior.</p>
A-0064	<p>(e)(2) A restraint can only be used if needed to improve the patient's well being and less restrictive interventions have been determined to be ineffective.</p> <p>(Ref. deleted tag A-0078)</p>	<p>(e)(2) Restraint or seclusion may only be used when less restrictive interventions have been determined to be ineffective to protect the patient, a staff member or others from harm.</p>
A-0065	<p>(e)(3) The use of a restraint must be—</p> <p>(i) Selected only when other less restrictive measures have been found to be ineffective to protect the patient or others from harm.</p>	<p>(e)(3) The type or technique of restraint or seclusion used must be</p> <p>the least restrictive intervention that will be effective to protect the patient, a staff member, or others from harm.</p> <p>(see tag A-0070)</p>
A-0070	<p>(e)(3)(iv) Implemented in the least restrictive manner possible.</p> <p>(see (e)(3))</p>	
		<p>(e)(4) The use of restraint or seclusion must be—</p>
A-0069	<p>(e)(3)(iii) In accordance with a written modification to the patient's plan of care;</p>	<p>(i) In accordance with a written modification to the patient's plan of care; and</p>

TAG	2006 Regulation	Regulation Effective January 8, 2007
	(Ref. deleted tag A-0086) (see (e)(4)(i))	(see tag A-0069)
		(ii) Implemented in accordance with safe and appropriate restraint and seclusion techniques as determined by hospital policy in accordance with State law.
A-0066	(e)(3)(ii) In accordance with the order of a physician or other licensed independent practitioner permitted by the State and hospital or order a restraint. This order must— (Ref. deleted tag A-0079)	(e)(5) The use of restraint or seclusion must be in accordance with the order of a physician or other licensed independent practitioner who is responsible for the care of the patient as specified under § 482.12(c) and authorized to order restraint or seclusion by hospital policy in accordance with State law.
A-0067	(e)(3)(ii) (A) Never be written as a standing or on an as needed basis (that is, PRN); and (Ref. deleted tag A-0080)	(e)(6) Orders for the use of restraint or seclusion must never be written as a standing order or on an as needed basis (PRN).
A-0068	(e)(3)(ii) (B) Be followed by consultation with the patient's treating physician, as soon as possible, if the restraint is not ordered by the patient's treating physician; (Ref. deleted tag A-0081)	(e)(7) The attending physician must be consulted as soon as possible if the attending physician did not order the restraint or seclusion .
A-0071	(e)(3)(v) In accordance with safe and appropriate restraining techniques, and	
		(e)(8) Unless superseded by State law that is more restrictive—
	(Ref. deleted tag A-0084)	(i) Each order for restraint or seclusion used for the management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others may only be renewed in accordance with the following limits for up to a total of 24 hours:
	(Ref. deleted tag A-0083)	(A) 4 hours for adults 18 years of age or older;
	(Ref. deleted tag A-0083)	(B) 2 hours for children and adolescents 9 to 17 years of age; or

TAG	2006 Regulation	Regulation Effective January 8, 2007
	(Ref. deleted tag A-0083)	(C) 1 hour for children under 9 years of age; and
	(Ref. deleted tag A-0085)	<p>(ii) After 24 hours, before writing a new order for the use of restraint or seclusion for the management of violent or self-destructive behavior,</p> <ul style="list-style-type: none"> • a physician or other licensed independent practitioner who is responsible for the care of the patient as specified under §482.12(c) of this part and authorized to order restraint or seclusion by hospital policy in accordance with State law • must see and assess the patient.
		<p>(iii) Each order for restraint used to ensure the physical safety of the nonviolent or non-self-destructive patient may be renewed as authorized by <u>hospital policy</u>.</p>
A-0072	(e)(3)(vi) Ended at the earliest possible time. (Ref. deleted tag A-0089)	(e)(9) Restraint or seclusion must be discontinued at the earliest possible time, regardless of the length of time identified in the order.
A-0073	(e)(4) The condition of the restrained patient must be continually assessed , monitored, and reevaluated .	<p>(e)(10) The condition of the patient who is restrained or secluded must be monitored by</p> <ul style="list-style-type: none"> • a physician, • other licensed independent practitioner or • trained staff that have completed the training criteria specified in paragraph (f) of this section at an interval determined by hospital policy.
A-0074	(e)(5) All staff who have direct patient contact must have ongoing education and training in the proper and safe use of restraints.	<p>(e)(11) Physician and other licensed independent practitioner training requirements must be specified in hospital policy.</p> <p><u>At a minimum</u>, physicians and other licensed independent practitioners authorized to order restraint or seclusion by hospital policy in accordance with State law must have a working knowledge of hospital</p>

TAG	2006 Regulation	Regulation Effective January 8, 2007
		policy regarding the use of restraint or seclusion.
	(Ref. deleted tag A-0082)	(e)(12) When restraint <u>or seclusion</u> is used for the management of <u>violent or self-destructive behavior</u> that jeopardizes the immediate physical safety of the patient, a staff member, or others, the patient must be seen face-to-face within 1 hour after the initiation of the intervention—
	(Ref. deleted tag A-0082)	(i) By a— (A) Physician or other licensed independent practitioner; or
		(B) <u>Registered nurse or physician assistant</u> who has been trained in accordance with the requirements specified in paragraph (f) of this section.
		(ii) To evaluate— (A) The patient's immediate situation;
		(B) The patient's reaction to the intervention;
		(C) The patient's medical and behavioral condition; and
		(D) The need to continue or terminate the restraint or seclusion.
		(e)(13) States are free to have requirements by statute or regulation that are more restrictive than those contained in paragraph (e)(12)(i) of this section.
		(e)(14) If the face-to-face evaluation specified in paragraph (e)(12) of this section is conducted by a <u>trained registered nurse or physician assistant</u>,

TAG	2006 Regulation	Regulation Effective January 8, 2007
		<p>the trained registered nurse or physician assistant must</p> <ul style="list-style-type: none"> consult the attending physician or other licensed independent practitioner who is responsible for the care of the patient as specified under § 482.12(c) as soon as possible after the completion of the 1-hour face-to-face evaluation.
	(Ref. deleted tag A-0090)	<p>(e)(15) All requirements specified under this paragraph are <u>applicable to the simultaneous use of restraint and seclusion.</u></p> <p>Simultaneous restraint and seclusion use is only permitted if the patient is continually monitored—</p>
	(Ref. deleted tag A-0090)	<p>(i) Face-to-face by an assigned, trained staff member; or</p>
	(Ref. deleted tag A-0091)	<p>(ii) By trained staff using both video and audio equipment. This monitoring must be in close proximity to the patient.</p>
		<p>(e)(16) When restraint or seclusion is used, there must be <u>documentation</u> in the patient's medical record of the following:</p>
		<p>(i) The 1-hour face-to-face medical and behavioral evaluation if restraint or seclusion is used to manage violent or self-destructive behavior;</p>
		<p>(ii) A description of the patient's behavior and the intervention used;</p>
		<p>(iii) Alternatives or other less restrictive interventions attempted (as applicable);</p>
		<p>(iv) The patient's condition or symptom(s) that warranted the use of the restraint or seclusion; and</p>

TAG	2006 Regulation	Regulation Effective January 8, 2007
		(v) The patient's response to the intervention(s) used, including the rationale for continued use of the intervention.
A-0075	§482.13 (f) Standard: Seclusion and Restraint for Behavior Management	(f) Standard: Restraint or seclusion: Staff training requirements.
A-0076	<p>Standard (f) (1) The patient has the right to be free from seclusion and restraints, of any form, imposed as a means of coercion, discipline, convenience, or retaliation by staff.</p> <p>The term "restraint" includes either a physical restraint or a drug that is being used as a restraint.</p> <p>A physical restraint is any manual method or physical or mechanical device, material, or equipment attached or adjacent to the patient's body that he or she cannot easily remove that restricts freedom of movement or normal access to one's body.</p> <p>A drug used as a restraint is a medication used to control behavior or to restrict the patient's freedom of movement, and is not a standard treatment for the patient's medical or psychiatric condition. (see Standard (e), (e)(1)(i)(A), and (e)(1)(i)(B))</p>	<p><i>Note:</i> <i>The content of the 2006 Standard (f) has been incorporated into the new 2007 Standard (e). The new 2007 Standard (f) has been completely re-written to address the issues of staff training. See below for the new requirements for Standard (f)</i></p>
A-0077	<p>Standard (f) (2) Seclusion or restraint can only be used in emergency situations if needed to ensure the patient's physical safety and less restrictive interventions have been determined to be ineffective.</p>	
A-0078	<p>Standard (f) (3) The use of a restraint or seclusion must be— (i) Selected only when less restrictive measures have been found to be ineffective to protect the patient or others from harm.</p>	
A-0079	<p>Standard (f) (3)(ii) In accordance with the order of a physician or other licensed independent practitioner permitted by the State and hospital to order seclusion or restraint. The following requirements will be superseded by existing State laws that are more restrictive:</p>	
A-0080	<p>Standard (f) (3)(ii)(A) Orders for the use of seclusion or a restraint must never be written as a standing order or on an as needed basis (that is, PRN).</p>	
A-0081	<p>Standard (f) (3)(ii)(B) The treating physician must be consulted as soon as possible, if the restraint or seclusion is not ordered by the patient's treating physician.</p>	
A-0082	<p>Standard (f) (3)(ii)(C) A physician or other licensed independent practitioner must see and evaluate the need for restraint or seclusion within 1 hour after the initiation of this intervention.</p>	

TAG	2006 Regulation	Regulation Effective January 8, 2007
A-0083	Standard (f) (3)(ii)(D) Each written order for a physical restraint or seclusion is limited to 4 hours for adults; 2 hours for children and adolescents ages 9 to 17; or 1 hour for patients under 9.	
A-0084	Standard (f) (3)(ii)(D) continued The original order may only be renewed in accordance with these limits for up to a total of 24 hours.	
A-0085	Standard (f) (3)(ii)(D) continued After the original order expires, a physician or licensed independent practitioner (if allowed under State law) must see and assess the patient before issuing a new order.	
A-0086	Standard (f) (3)(iii) In accordance with a written modification to the patient's plan of care;	
A-0087	Standard (f) (3)(iv) Implemented in the least restrictive manner possible;	
A-0088	Standard (f) (3)(v) In accordance with safe appropriate restraining techniques; and	
A-0089	Standard (f) (3)(vi) Ended at the earliest possible time.	
A-0090	Standard (f) (4) A restraint and seclusion may not be used simultaneously unless the patient is— (i) Continually monitored face-to-face by an assigned staff member; or	
A-0091	Standard (f) (4)(ii) Continually monitored by staff using both video and audio equipment. This monitoring must be in close proximity to the patient.	
A-0092	Standard (f) (5) The condition of the patient who is in a restraint or in seclusion must continually be assessed, monitored, and reevaluated.	
A-0093	Standard (f) (6) All staff who have direct patient contact must have ongoing education and training in <ul style="list-style-type: none"> the proper and safe use of seclusion and restraint application and techniques and 	Standard (f): Restraint or seclusion: Staff training requirements. The patient has the right to safe implementation of restraint or seclusion by trained staff.
A-0094	Standard (f) (6) continued [All staff who have direct patient contact must have ongoing education and training in] <ul style="list-style-type: none"> alternative methods for handling behavior, symptoms and situations that traditionally have been treated through the use of restraints or seclusion 	(f)(1) Training intervals. Staff must be trained and able to demonstrate competency in the <ul style="list-style-type: none"> application of restraints, implementation of seclusion, monitoring, assessment, and providing care for a patient in restraint or seclusion— (Ref. deleted tags A-0092 & A-0093)


TAG	2006 Regulation	Regulation Effective January 8, 2007
		(i) Before performing any of the actions specified in this paragraph;
		(ii) As part of orientation; and
		(iii) Subsequently on a periodic basis consistent with hospital policy.
		(f)(2) <u>Training content.</u> The hospital must require appropriate staff to have <ul style="list-style-type: none"> • education, • training, and • demonstrated knowledge based on the specific needs of the patient population in at least the following:
	(Ref. deleted tag A-0094)	(i) <u>Techniques</u> to identify <ul style="list-style-type: none"> • staff and patient behaviors, • events, and • environmental factors that may trigger circumstances that require the use of a restraint or seclusion
	(Ref. deleted tag A-0094)	(ii) The use of nonphysical intervention skills.
	(Ref. deleted tag A-0094)	(iii) <u>Choosing the least restrictive</u> intervention based on an individualized assessment of the patient's medical, or behavioral status or condition.
	(Ref. deleted tag A-0093)	(iv) The <u>safe application</u> and use of all types of restraint or seclusion used in the hospital, including training in how to recognize and respond to signs of physical and psychological distress (for example, positional asphyxia);
		(v) <u>Clinical identification</u> of specific behavioral changes that indicate that restraint or seclusion is no longer necessary.

TAG	2006 Regulation	Regulation Effective January 8, 2007
		<p>(vi) <u>Monitoring</u> the physical and psychological well-being of the patient who is restrained or secluded, including but not limited to,</p> <ul style="list-style-type: none"> • respiratory and circulatory status, • skin integrity, • vital signs, and • any special requirements specified by hospital policy associated with the 1-hour face-to-face evaluation.
		<p>(vii) The use of</p> <ul style="list-style-type: none"> • first aid techniques and • certification in the use of cardiopulmonary resuscitation, • including required periodic recertification.
		<p>(f)(3) <u>Trainer requirements.</u> Individuals providing staff training must be qualified as evidenced by</p> <ul style="list-style-type: none"> • education, • training, and • experience in techniques used to address patients' behaviors.
		<p>(f)(4) <u>Training documentation.</u> The hospital must document in the staff personnel records that the training and demonstration of competency were successfully completed.</p>
		<p>(g) <u>Standard: Death reporting requirements:</u></p>
A-0095	<p>(f)(7) The hospital must report to CMS any death that occurs while a patient is restrained or in seclusion, or where it is reasonable to assume that a patient's death is a result of restraint or seclusion.</p>	<p>Hospitals must report deaths associated with the use of seclusion or restraint.</p>
		<p>(g)(1) The hospital must report the following information to CMS:</p>
		<p>(i) Each death that occurs while a patient is in restraint or seclusion.</p>

TAG	2006 Regulation	Regulation Effective January 8, 2007
		(ii) Each death that occurs within 24 hours after the patient has been removed from restraint or seclusion.
		(iii) Each death known to the hospital that occurs within 1 week after restraint or seclusion where it is reasonable to assume that use of restraint or placement in seclusion contributed directly or indirectly to a patient's death. “Reasonable to assume” in this context includes, but is not limited to, deaths related to restrictions of movement for prolonged periods of time, or death related to chest compression, restriction of breathing or asphyxiation.
		(g)(2) Each death referenced in this paragraph must be reported to CMS by telephone no later than the close of business the next business day following knowledge of the patient's death.
		(g)(3) Staff must document in the patient's medical record the <u>date and time</u> the death was <u>reported to CMS</u>.

OQA/LAR 12/06, 1/07

Key:

Red = differences between the 2006 and 2007 regulations = omitted from the new regulation

Source: **Federal Register** / Vol. 71, No. 236 / Friday, December 8, 2006 / Rules and Regulations, Pages 71426-71428

<http://a257.g.akamaitech.net/7/257/2422/01jan20061800/edocket.access.gpo.gov/2006/pdf/06-9559.pdf> (exit DHFS)